



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1459]

Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period in the notice of availability that appeared in the Federal Register of February 19, 2015. In that notice of availability, FDA requested comments on a draft standard memorandum of understanding (MOU) entitled “Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration.” The draft standard MOU describes the responsibilities of any State that chooses to sign the MOU in investigating and responding to complaints related to compounded human drug products distributed outside the State and in addressing the interstate distribution of inordinate amounts of compounded human drug products. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period in the notice of availability published on February 19, 2015 (80 FR 8874) which includes comment on information collection issues under

the Paperwork Reduction Act of 1995 (the PRA). Submit either electronic or written comments on the draft standard MOU or on information collection issues under the PRA by July 20, 2015.

ADDRESSES: Submit written requests for single copies of the MOU to Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993-0002. Send one self-addressed label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft standard MOU.

Submit electronic comments on the new draft standard MOU or on the collection of information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993-0002, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 19, 2015 (80 FR 8874), FDA published a notice of availability of a draft standard MOU entitled “Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration” with a 120-day comment period to request comments on the draft standard MOU. The draft standard MOU describes the responsibilities of any State that chooses to sign the MOU in: (1) Investigating and responding to complaints related to compounded human drug products distributed outside the State and (2) addressing the

interstate distribution of inordinate amounts of compounded human drug products. Comments were also requested on information collection issues under the PRA. The notice of availability also announced the withdrawal, effective February 19, 2015, of an earlier draft standard MOU entitled “Memorandum of Understanding on Interstate Distribution of Compounded Drug Products” that published on January 21, 1999 (64 FR 3301). The January 1999 draft standard MOU is superseded by the February 2015 draft standard MOU.

The Agency is extending the comment period both for the draft standard MOU and for information collection issues under the PRA for 30 days, until July 20, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying resolution of these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft standard MOU at <http://www.regulations.gov>.

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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